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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	19

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,052	RAITANO ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication app ars on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-72 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restrictions

I. Claims 1-3, drawn to a method for monitoring 85P1B3 gene products in a biological sample from a patient who has or who is suspected of having cancer, classified in class 435, subclasses 6, 7.1, for examples.

II. Claims 4-12, 46 and 54-55, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises a 85P1B3-related protein, and methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, classified in class 424, subclass 184.1.

III. Claims 4-6, 14-21, 23-24, 46, 48, 54 and 56, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises an antibody or fragment thereof that specifically binds to a 85P1B3-related protein, methods for inhibiting growth or treating a patient who bears

cancer cells expressing 85P1B3 using the same, and a hybridoma that produces the same antibody, classified in class 424, subclass 130.1.

IV. Claims 4-6, 25, 27, 46, 49, 54 and 57-58, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises a polynucleotide that encodes a single chain monoclonal antibody that immunologically binds to a 85P1B3-related protein, methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, and a vector comprising a polynucleotide that encodes the same single chain monoclonal antibody, classified in class 514, subclass 44.

V. Claims 4-6, 13, 28-36, 46, 50, 54 and 59, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises a polynucleotide that comprises an 85P1B3-related protein coding sequence, methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, and a vector comprising a polynucleotide that encodes an anolog peptide of 8, 9, 10 or eleven contiguous amino acids of Figure 2, classified in class 514, subclass 44.

VI. Claims 4-6, 37-43, 46, 51, 54 and 60, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises a polynucleotide that is fully complementary to a polynucleotide that comprises an 85P1B3 – related protein coding sequence, methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, and a composition comprising the same polynucleotide, classified in class 514, subclass 44.

VII. Claims 4-6, 44, 46, 52, 54 and 61, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises a ribozyme that cleaves a polynucleotide having 85P1B3 coding sequence, methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, and a composition comprising the same ribozyme, classified in class 514, subclass 44.

VIII. Claims 4-6, 45-46, 53-54 and 62, drawn to a composition comprising a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated, and wherein the substance comprises human T cells wherein the T cells specifically recognize an 85P1B3 peptide sequence in

the context of a particular HLA molecule, methods for inhibiting growth or treating a patient who bears cancer cells expressing 85P1B3 using the same, and a composition comprising the same human T cells, classified in class 424, subclass 93.71.

IX. Claims 63-67, drawn to a method of generating a mammalian immune response directed to 85P1B3, the method comprises exposing cells of the mammal's immune system to an immunogenic portion of an 85P13 related protein, whereby an immune response is generated to 86P1B3, classified in class 424, subclass 184.1.

X. Claims 63-67, drawn to a method of generating a mammalian immune response directed to 85P1B3, the method comprises exposing cells of the mammal's immune system to a nucleotide sequence that encodes an 85P13 related protein, whereby an immune response is generated to 86P1B3, classified in class 514, subclass 44.

XI. Claims 68-70, drawn to an assay for detecting the presence of an 85P1B3-related protein in a biological sample from a patient who has or who is suspected of having cancer using an antibody that specifically binds to the 85P1B3-related protein, classified in class 435, subclass 7.1.

XII. Claims 68, 70-71, drawn to an assay for detecting the presence of an 85P1B3-related polynucleotide in a biological sample from a patient who has or who is suspected of having cancer using a polynucleotide probe that specifically hybridizes to a polynucleotide encoding an 85P1B3-

related protein having the amino acid sequence of Figure 2, classified in class 435, subclass 6.

XIII. Claims 68 and 72, drawn to an assay for detecting the presence of 85P1B3 mRNA in a biological sample from a patient who has or who is suspected of having cancer using RT-PCR approach, classified in class 435, subclass 91.2.

XIV. Claim 22, drawn to a non-human transgenic animal that produces an antibody that specifically binds to a 85P1B3-related protein, classified in class 800, subclass 4.

Claims 4-6 link patentably distinct inventions of Groups II-VIII that lack the unity of invention. This is because substances that modulate the status of 85P1B3 such as: (i) a 85P1B3-related protein, (ii) an antibody or fragment thereof that specifically binds to a 85P1B3-related protein, (iii) a polynucleotide that encodes a single chain monoclonal antibody that immunologically binds to a 85P1B3-related protein, (iv) a polynucleotide that comprises an 85P1B3-related protein coding sequence, (v) a polynucleotide that is fully complementary to a polynucleotide that comprises an 85P1B3-related protein, (vi) a ribozyme that cleave a polynucleotide having 85P1B3 coding sequence, and (vii) human T cells that specifically recognize an 85P1B3 peptide sequence in the context of a particular HLA molecule are distinct, and there is no substantial common structural features shared among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a

common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Similarly, claims 63-67 link patentably distinct inventions of Groups IX-X that lack the unity of invention. This is because an immunogenic portion of an 85P13-related protein (made up of amino acid residues) and a nucleotide sequence that encodes an 85P13-related protein (made up of nucleotides) are chemically distinct molecules having no substantial common structural features to be utilized in a method for generating a mammalian immune response. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Similarly, claims 68-70 link patentably distinct inventions of Groups XI-XIII that lack the unity of invention. This is because a substance that specifically binds to the 85P1B3-related protein (an antibody) and a substance that specifically binds to the 85P1B3-related polynucleotide (a polynucleotide probe or sense and anti-sense primers) are chemically distinct molecules having no substantial common structural features to be utilized in an assay for detecting the presence of a 85P1B3-related protein or polynucleotide. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Additionally, should Applicants elect the invention of Group II, **further group restriction** is required. Claims 4-12, 46 and 54-55 link patentably distinct inventions that lack the unity of invention. This is because the CTL polypeptide epitopes selected

from Tables V-XVIII containing 700 different SEQ ID NOs., have distinct amino acid sequences that have no substantial common core structure among themselves and they also have different biological activities. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Accordingly, Applicant is required to elect a specific CTL polypeptide epitope selected from Tables V-XVIII.

Additionally, should Applicants elect the invention of Group V, **further group restriction** is required. Claims 4-6, 13, 28, 35-36, 46, 50, 54 and 59 link patentably distinct inventions that lack the unity of invention. This is because a polynucleotide that encodes at least one peptide selected from Tables V-XVIII containing 700 different SEQ ID NOs., wherein each encoded peptide has a distinct amino acid sequence having no substantial common core structure one from the others and each encoded peptide also has a different biological activity. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Accordingly, Applicant is required to elect a polynucleotide that encodes at least a specific peptide from Tables V-XVIII.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-XIII are distinct one from the others as they are drawn to methods having different starting materials, different method steps and therefore they require different technical considerations for achieving different desired end-results. For examples, the method of monitoring 85P1B3 gene products in a biological sample of Group I, the assay methods for detecting the presence of an 85P1B3-related protein in a biological sample of Groups XI-XIII, the methods of generating a mammalian immune response directed to 85P1B3 of Groups IX-X do not require to inhibit growth of cancer cells or to treat a patient bearing cancer cells as the methods of Groups II-VIII. Additionally, the methods of Groups I-XIII can be carried out independently one from the others.

The compositions of Groups II-VIII are chemically and structural distinct for the reasons already set forth above. Additionally, none of these compositions share any substantial structural feature with a non-human transgenic animal that produces an antibody that specifically binds to a 85P1B3-related protein of Group XIV.

Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substance comprising an antibody or fragment thereof that specifically binds to a 85P1B3-related protein can be used either in methods of inhibiting cancer growth or treating a patient who bears cancer cells of Group III or in an assay for detecting the presence of an 85P1B3-related protein in a biological sample of Group XI.

Inventions VI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substance comprising a polynucleotide that is fully complentary to a polynucleotide that comprises a 85P1B3-related protein coding sequence can be used either in methods of inhibiting cancer growth or treating a patient who bears cancer cells of Group VI or in an assay for detecting the presence of an 85P1B3-related polynucleotide in a biological sample of Group XII.

The different inventions above have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature

search. Additionally, because of limited resources from the USPTO to conduct the computer search of the claimed SEQ ID NOs listed in Tables V-XVIII, and all of the SEQ ID NOs do not possess a common core structure or element, an undue burden would be needed to search and examine all of the claimed inventions in a single application, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements (e.g., different classification), it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species restriction

A. Should Applicants elect Group I, claims 1-3 are generic to a plurality of disclosed distinct species comprising:

A specifically named cancer set forth in Table 1 as recited in claim 3.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

B. Should Applicants elect either Group IX or Group X, claims 63-64 are generic to a plurality of disclosed distinct species comprising:

(a) a T cell epitope, or (b) a B cell epitope.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

PATENT EXAMINER
A.U. 1636